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Noritada Katayama

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EXAMINER

SYED, ATIA K

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3769

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,509	Applicant(s) KATAYAMA, NORITADA	
	Examiner ATIA SYED	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 12, 18, 22, 24, 26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 12, 18, 22, 24, 26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/18/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner acknowledges the response filed on June 18, 2009.

Note to Applicant Regarding Claim Interpretation

The word “for” and the phases “configured to” and “adapted to” in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb US Patent Number 3,651,694 in view of Alvarez US Patent Number 6,238,354.

In regards to **claim 22**, Lamb discloses a biological information monitoring system comprising a plurality of biological information sensor modules adapted to be attached to the right side and left side of a subject body, said biological information sensor modules each incorporating a biological information sensor for detecting biological information and a

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communicator configured to communicate said biological information, wherein said plurality of biological information sensor modules includes at least a first biological information sensor module and a second biological information sensor module, wherein said first biological information sensor module includes an integrated circuit including a measurement calculating unit configured to determine an abnormality by comparing said biological information detected by said biological information sensor in the first biological information sensor module itself with biological information sent from said second biological information sensor module through said biological information sensor module through said communicator, wherein said biological information detected by said biological information sensor is *at least one of* body temperature (temperature probe; column 1, lines 30-75; *applicant is advised that only one of the sensors is positively recited i.e. as long as Lamb disclose only one of the three sensor it anticipates the claim*), pulse and blood pressure, wherein a pulse difference equal to or greater not less than 7 beats per minute between the pulses measured on the right and left sides of the subject is determined as abnormal by said measurement calculating (*since pulse sensor is not positively recited, Examiner does not need to find this limitation*).

Lamb does not disclose that the biological sensor modules each incorporate a communicator for communicating said biological information by wireless. Lamb also does not disclose that at least one of said biological information sensor modules includes the determination means for performing determination of abnormality by comparing said biological information detected by said biological information sensor in the biological information sensor module itself with biological information sent from the other biological information sensor module through said communicator.

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However Alvarez, a reference in an analogous art, discloses a temperature monitoring assembly for continuously monitoring a patient from a remote location with two biological information sensor modules on a user's left and right arms wherein the determination means for calculating the temperature is on one sensor module. The determination means averages biological information detected by said biological information sensor in the biological information sensor module itself with biological information sent from the other biological information sensor module using wireless communication (Alvarez; Fig. 4, column 2, lines 1-45, column 7, lines 5-34).

It would have been obvious to one having ordinary skill in the art to substitute the wired sensor modules of Lamb with Alvarez's wireless temperature monitoring assembly because Alvarez teaches that the wireless device allows for continuous remote monitoring of body temperature of a patient such as a small child during the night or while sleeping and this is important because if onset of increased temperatures are allowed to go unobserved they can result in permanent damage to a patient (Alvarez; column 2, lines 5-10 and lines 35-40).

9. The biological information monitoring system set forth in claim 22, wherein at least one of said biological information sensor modules incorporates a memory for storing at least one of a determination result outputted from said measurement calculating unit and the biological information measured by said biological information sensor (Alvarez Column 5, lines 60-67, reset button has to erase the data, therefore the data must be stored in memory in order to be erased).

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24. The biological information monitoring system set forth in claim 22, wherein said system further comprises a warning unit for issuing a warning when said measurement calculating unit detects an abnormality (Lamb; alarm arrangement, column 3, lines 15-37).

26. The biological information monitoring system set forth in claim 22, wherein at least one of the biological information sensor incorporates a communicator for communicating with the outside to release a determination result of said measurement calculating unit by wireless, and wherein said system comprises an external electronic device for receiving said determination result outputted from said measurement calculating unit (Alvarez; Figure 5, column 4, lines 65-67, column 5, lines 1-15).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb in view of Alvarez as applied to claim 26 above, and further in view of Besson et al. US Patent Number 5,862,803 (hereinafter Besson).

In regards to claim 18, Lamb, Alvarez and JNS do not disclose that the biological information monitoring system set forth in claim 26, wherein said communicator transmits identification signals for distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and said determination result, to thereby identify the individual living subjects.

However Besson, a reference in an analogous art, discloses a wireless medical diagnosis system with biological sensor modules (Besson; Abstract and column 13, lines 25-45). Each

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module is assigned an identification code corresponding to the patient to whom it is attached. An external device can then differentiate between data received from different patients' sensor modules by using the identification code received with the data (Besson; Column 8, lines 5-25). This is equivalent to the claim limitation of wherein said communicator transmits identification signals for distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects.

It would have been obvious to one of ordinary skill in the art at the time of invention to improve the invention of Lamb and Alvarez by using Besson's technique of having identification codes for each sensor module corresponding to the patient to whom the sensor module is attached such that the external device receiving data can use the received identification code to differentiate between data from different patients and their sensor modules because it would provide the benefit of preventing confusion between different patients' data and make the device capable of simultaneously serving several patients in a room (Besson; Column 8, lines 5-25).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb in view of Alvarez as applied to claim 22 above and further in view of Journal of Nursing Science, December 31, 1990 (Hereinafter JNS, provided in IDS).

In regards to claim 28, Lamb modified by Alvarez in claim 22 discloses actuating an alarm when the temperature difference is greater than or equal to 5 degrees (*Lamb column 3, lines 24-35*).

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Lamb modified by Alvarez does not disclose wherein a temperature difference not lower than 0.5 °C between the body temperatures measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit.

However JNS, a reference in an analogous art, discloses that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C 9 (this meets the limitation not lower than 0.5 degrees C) patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Lamb and Alvarez by switching the temperature different that sets off an alarm from greater than 5 degrees to greater than 0.6 degrees as taught by JNS, because JNS teaches that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C 9 patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*).

Claims 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. US Patent Number 5,724,980 (hereinafter Nakamura) in view of Inagaki et al. US Patent Number 6,344,025 (hereinafter Inagaki).

In regards to claim 22, Nakamura discloses a biological information monitoring system comprising:

a plurality of biological information sensor modules adapted to be attached to the right side and left side of a subject body (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines

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1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module),

said biological information sensor modules each incorporating a biological information sensor for detecting biological information (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure),

wherein said plurality of biological information sensor modules includes at least a first biological information sensor module and a second biological information sensor module (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module),

wherein said first biological information sensor module includes a measurement calculating unit configured to determine an abnormality by comparing said biological information detected by said biological information sensor in the first biological information sensor module itself with biological information sent from said second biological information sensor module (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. Sensor portion 11b connected with processor 2 comprises the sensor module with determination means because the processor determines whether the difference between the two blood pressures measurements is over a predetermined value),

wherein said biological information detected by said biological information sensor is **at least one of** body temperature, pulse and *blood pressure* (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure),

wherein a pulse difference equal to or greater not less than 7 beats per minute between the pulses measured on the right and left sides of the subject is determined as abnormal by said

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measurement calculating (*since pulse sensor is not positively recited, Examiner does not need to reject this limitation*).

Nakamura further discloses that the two sensors/blood pressure cuffs send information via a wired connection (Nakamura; Fig. 1).

Nakamura does not disclose that the sensors/blood pressure cuffs include a communicator configured to communicate said biological information by wireless and that the information is sent from one biological information sensor module to another through said communicator.

However Inagaki, a reference in an analogous art discloses a blood pressure monitor where a cuff is provided with transmission and reception portions (equivalent to a communicator) to communicate measured signals wherein the communications are wired or wireless (Inagaki column 1, lines 60-67 and column 4, lines 35-45). Both references disclose blood pressure cuffs for determining a user's blood pressure.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nakamura's blood pressure measuring cuffs that communicate via a wired connection with Inagaki's cuff including transmission and reception portions (equivalent to a communicator) for communicating measured signals wirelessly because Inagaki teaches that a wireless connection improves operability of the blood pressure monitoring device (Inagaki column 2, lines 18-22).

12. The biological information monitoring system set forth in claim 22, wherein said system further comprises an electronic device for transmitting data to said biological information sensor module by wireless, and wherein said measurement calculating unit performs abnormality

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determination with reference to said data sent from said electronic device (Nakamura as modified by Inagaki for the rejection of claim 22 above would have two blood pressure cuffs communicating wirelessly where the processor compares data from both to determine whether the difference between the two blood pressures measurements is over a predetermined value. The cuff without the processor would meet the limitation of an electronic device for transmitting data to said biological information sensor module by wireless, so as to perform abnormality determination with reference to said data sent from said electronic device in said determination means).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura in view of Inagaki as applied to claim 22 above and further in view of *Journal of Brain and Nervous Diseases*, December 31, 1996 (Hereinafter JBND, provided in IDS).

In regards to claim 29, Nakamura modified in view of Inagaki in claim 22 would have a processor that compares data from both right and left cuffs to determine whether the difference between the two blood pressures measurements is over a predetermined value and display a warning in that case (Nakamura column 3, lines 1-19).

Nakamura and Inagaki do not disclose a particular number for the predetermined value and therefore do not disclose the limitation wherein a blood pressure difference not less than 10 mmHg between the blood pressures measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit.

However JBND, a reference in an analogous art, discloses that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg (this meets “not less

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than 10 mmHg” because it is greater) is of important clinical significance (JBND page 3, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Nakamura and Inagaki to set the predetermined difference value to cause a warning at greater than 15mmHg as taught by JBND, because JBND teaches that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg is of important clinical significance (JBND page 3, lines 1-4).

Response to Arguments

Applicant's arguments with respect to the allowability of claim 22 and the dependent claims thereof have been considered. During a telephone interview, Examiner identified the following limitation as allowable subject matter:

“pulse difference equal to or greater not less than 7 beats per minute between the pulses measured on the right and left sides of the subject is determined as abnormal by said measurement calculating”

However, claim 22 as currently recited does not require the Examiner to reject the above identified limitation because claim 22 only requires the Examiner to find one of the temperature, pulse or blood pressure sensors. During a telephone conversation Examiner Syed and Examiner Naqi suggested that in order to improve the chances of the allowability of claim 22 Applicant should positively recite the allowable subject matter i.e. positively claim a “pulse sensor”. The telephone conversation did not resolve the above identified issue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ATIA SYED whose telephone number is (571)270-7134. The examiner can normally be reached on Monday through Friday, 9:00-5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ATIA SYED/
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

September 16, 2009